

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/573,039 (Q93989)

REMARKS

Claim 1 has been amended, and claim 2 is hereby cancelled. Support for the amendments to claim 1 can be found in cancelled claim 2. Hence, the amendments to claim 1 does not constitute new matter, and thus entry is respectfully requested.

Response to Rejections

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 and 5 of U.S. Patent No. 6,190,637 to Ino *et al.* (hereinafter referred to as “the ‘637 Patent”) in view of Toorongian *et al.* (Routine Production of 2-Deoxy-2-[18F]fluoro-D-glucose by Direct Nucleophilic Exchange on a Quaternary 4-Aminopyridinium Resin; Nucl. Med. Biol.; Vol. 17, No. 3, pages 273-279; 1990) (hereinafter referred to as “Toorongian *et al.*”). Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the ‘637 Patent in view of Toorongian *et al.*

The Examiner’s rejection is based on essentially the same grounds of rejection as discussed in the Non-final office action dated December 22, 2008. Further, regarding Applicant’s arguments filed on March 19, 2009, the Office Action states that Applicants arguments are not persuasive because Toorongian *et al.* was relied upon to teach a quaternary amine which allows for the combination of collection steps, not for the exact structure taught by Toorongian *et al.* In other words, the Office Action states that Toorongian *et al.* was asserted to (1) show that it is known in the art to use quaternary amines for chromatography and; (2) the reason one of ordinary skill in the art would modify ‘637 Patent to use a quaternary amine instead of a tertiary amine.

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
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Applicants respectfully traverse the rejection. Initially, Claim 1 has been amended to more specifically recite that formula of the ion exchange resin, wherein n is 1; R is a linear butyl group; P is a polystyrene-divinylbenzene copolymer; and Y is CO_3^{2-} or HCO_3^- . The cited references fail to teach or suggest Applicant's invention, as amended.

The '637 Patent and claims disclose a method for preparing [^{18}F]-fluoride ion wherein the [^{18}O]-enriched water is contacted with a strongly acidic cation exchange resin and a weakly basic anion exchange resin, neither of which are the claimed resin formula. Toorongian *et al.* disclose a 4-aminopyridium anion exchange resin. The resin disclosed in Toorongian *et al.* is not a tetra alkyl ammonium resin, as claimed in Formula I, wherein n is 1; R is a linear butyl group; P is a polystyrene-divinylbenzene copolymer; and Y is CO_3^{2-} or HCO_3^- . Applicants note that in order to establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. § 2143. Neither the '637 Patent nor Toorongian *et al.* teach or suggest all the claimed limitations, specifically an ion exchange resin wherein n is 1, R is a linear butyl group, Y is CO_3^{2-} or HCO_3^- and P is a polystyrene-divinylbenzene copolymer.

Further, it appears that the Office Action did not consider Applicant's arguments regarding unexpected results. In determining obviousness, *Graham* and subsequent decisions of the U.S. Court of Appeals for the Federal Circuit² hold that certain "objective" evidence relating to obviousness also must be considered. Such objective evidence includes unexpected results,

² See *Akzo N.V. v. United States Int'l Trade Comm.*, 808 F.2d 1471, 1481, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/573,039 (Q93989)

commercial success, a long existing problem that went unsolved, failures of others to achieve the invention, and industry recognition of the claimed invention. M.P.E.P. §2142 and §2143.03.

The claimed invention, reciting the formula of the claimed ion exchange resin, is not obvious at least in view of the unexpectedly high production yields of fluorine compound, when compared to the yields of fluorine compounds produced by the method of Tooongian *et al.* Specifically, Table 1 of the instant specification teaches that fluoride ion resin collection rate for 1 gram of [¹⁸F]-containing [¹⁸O] water was 100 percent and for 5 grams of [¹⁸F]-containing [¹⁸O] water, the collection rate was 98.3, which are greater than the trapping efficiency results provided in Table 1 of the Toorongian *et al.* publication. The specification, at page 23, also compares the resin of the present invention with a comparative resin manufactured by Sigma Aldrich, wherein the chloride ion was substituted with a carbonate ion. The table shows that resin of the present invention was able to achieve a high [¹⁸F] fluoride ion collection rate and high [¹⁸F]-TAFDG labeling index for a broad [¹⁸O] water treatment amount from 1g to 12g. For example, the fluoride ion resin collection rate for the resin of the present invention at 12g was 92.6 percent, compared to 24.5 percent for the comparative resin. Thus, one of ordinary skill in the art would not have expected, nor reasonably predicted, that the resin as described in formula 1, as amended, would produce unexpectedly high yields of fluorine compound, considering the yields disclosed in the art for other methods using different resins were significantly lower.

Accordingly, Applicants have disclosed the superiority of the resin of the claimed invention for collecting a high [¹⁸F] fluoride ion collection. As such, it is believed that the rejections of claims 1 and 3 are not sustainable.

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/573,039 (Q93989)

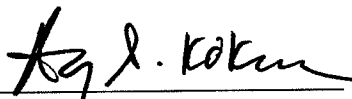
Withdrawal of the rejections and favorable reconsideration of the application are respectfully requested.

III. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The U.S. Patent and Trademark Office is hereby directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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